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By: Lewis J. Krosler
Lewis J. Krosler
Reg. No. 38522

Date: 3/31/04

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	John C. Bell, et al.	Atty. Ref	18003-D1
Appl. No.:	10/743,639	Group Art Unit:	1645
Filed:	December 22, 2003	Examiner:	Robert A. Zeman
Title:	ONCOLYTIC VIRUS		

* * * * *

March 31, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

INFORMATION DISCLOSURE STATEMENT

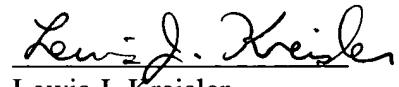
Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Examiner is directed to the documents listed on the enclosed Form PTO-1449. Copies of the listed documents are in the parent application serial number 09/664,444 and are therefore not being submitted with this Information Disclosure Statement.

This Communication is being filed within three months of the filing date or before the mailing of a first Office Action on the merits. Consideration of this Statement is respectfully requested.

Inventor(s): Bell, et al.
Application No.: 10/743,639
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It is believed that no fee is required in connection with the filing of this Statement. If any fee is required, the Commissioner is hereby authorized to charge the amount of such fee to Deposit Account No. 50-1677.

Respectfully submitted,


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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	10/743,639
		Filing Date	December 22, 2003
		First Named Inventor	John C. Bell
		Art Unit	1645
		Examiner Name	Robert A. Zeman
Sheet	1	of	14
		Attorney Docket Number	

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ⁴ -Number ⁴ - Kind Code ⁵ (if known)			
		WO 97/01358	01-1997		
		WO 97/04805	02-1997		
		WO 94/18992	09/1994		
		WO 99/08692	02-25-1999		
		WO 94/25627	11-1994		
		JP (A) 58-116422	07-1983		
		WO 93/18790	09-30-1993		
		WO 86/00811	02-13-1986		
		WO 86/00529	01-30-1986		
		WO 99/29343	06-17-1999		

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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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		WO 99/55345	11-04-1999		
		WO 00/45853	08-10-2000		
		EP 0 564 121 A2	10-06-1993		
		GB 1,069,144	05-17-1967		
		WO 99/04026	01-28-1999		
		WO 99/18799	04-22-1999		
		WO 97/26904	07-31-1997		
		WO 96/03997	02-15-1996		
		WO 95/32706	12-07-1995		
		WO 89/07554	08-24-1989		

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Sheet 4 of 14

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Filing Date	December 22, 2003
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Group Art Unit	1645
Examiner Name	Robert A. Zeman
Attorney Docket Number	18003-D1

NON PATENT PUBLICATIONS

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		Kirn, et al., "Replicating Viruses as Selective Cancer Therapeutics", Molecular Medicine Today, pages 519-527, December 1996.	
		Heise, et al., "Onyx-015, an E1B gene-attenuated adenovirus, causes tumor-specific cytolysis and antitumoral efficacy that can be augmented by standard chemotherapeutic agents", Nature Medicine, Vol 3, No. 6, pages 639-645, June 1997.	
		Zhang, et al. "Treatment of a human breast cancer xenograft with an adenovirus vector containing an interferon gene results in rapid regression due to viral oncolysis and gene therapy", Proc. Natl. Acad. Sci. USA, Vol 93, pages 4513-4518, April 1996.	
		Katze, "Regulation of the interferon-induced PKR: can viruses cope?", Trends in Microbiology, Vol. 3, No. 2, pages 75-78, February 1995.	
		Maheshwari, et al., "Low Infectivity of Vesicular Stomatitis Virus (VSV) Particles Released from Interferon-Treated cells is Related to Glycoprotein Deficiency", Biochemical and Biophysical Research Communications, Vol. 117, No 1, pages 161-168, November 30, 1983.	
		Chou, et al., "Association of a Mr 90,000 phosphoprotein with protein kinase PKR in cells exhibiting enhancing phosphorylation of translation ...simplex virus 1", Proc. Natl. Acad. Sci. USA, Vol 92, pages 10516-10520, November 1995.	
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		Linge, et al., "Interferon System Defects in Human Malignant Melanoma", Cancer Research, Vol. 55, pages 4099-4104, September 15, 1995.	
		Machida, et al. "Effective of Nucleosides on Interferon Production and Development of Antiviral State Induced by Poly I-Poly C", Microbiol. Immunol., Vol. 23 (7), pages 643-650, 1979	

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Sheet 5 of 14

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Examiner Name	Robert A. Zeman
Attorney Docket Number	18003-D1

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		Tanaka, et al., "Cellular Commitment to Oncogene-Induced Transformation or Apoptosis is Dependent on the Transcription Factor IRF-1", Cell, Vol. 77, pages 829-839, June 17, 1994.	
		Pennisi, "Will a Twist of Viral Fate Lead to a New Cancer Treatment?", Science, Vol. 274, Pages 342-343, October 18, 1996.	
		Bischoff, et al., "An Adenovirus Mutant that Replicates Selectively in p53-Deficient Human Tumor Cells", Science, Vol. 274, pages 373-376, October 18, 1996.	
		Andreansky, et al., "The application of genetically engineered herpes simplex viruses to the treatment of experimental brain tumors", Proc. Natl. Acad. Sci. USA, Vol. 93, pages 11313-11318, October 1996. Colloquium Paper	
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		Buller, et al., "Cell Proliferative Response to Vaccinia Virus Is Mediated by VGF", Virology, Vol. 164, pages 182-192. 1988.	
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		Haines, et al., "Correlation of the expression of double-stranded RNA-dependent protein kinase (p68) with differentiation in head and neck squamous cell carcinoma", Virchows Archiv B Cell Pathology, Vol. 63, pages 289-295, 1993	
		James, et al., "Chromosome 9 Deletion Mapping Reveals Interferon α and Interferon B-1 Gene Deletions in Human Glial Tumors", Cancer Research, Vol 51, pages 1684-1688, March 15, 1991.	

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Sheet 6 of 14

Complete if Known

Application Number	10/743,639
Filing Date	December 22, 2003
First Named Inventor	John C. Bell
Group Art Unit	1645
Examiner Name	Robert A. Zeman
Attorney Docket Number	18003-D1

NON PATENT PUBLICATIONS

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		Arroyo, et al., "Active specific immunotherapy with vaccinia colon oncolysate enhances the immunomodulatory and antitumor effects of interleukin-2 and interferon x in a murine hepatic metastasis model", <i>Cancer Immunology Immunotherapy</i> , Vol. 31, pages 305-311, 1990.	
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		Korth, et al., "Cloning, expression, and cellular localization of the oncogenic 58-kDa inhibitor of the RNA-activated human and mouse protein kinase", <i>Gene</i> , Vol. 170, pages 181-188, 1996.	
		Barber, et al., "The 58-kilodalton inhibitor of the interferon-induced double-stranded RNA-activated protein kinases is tetratricopeptide repeat protein with oncogenic properties", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 91, pages 4278-4282, May 1994.	
		Matthews, et al., "Adenovirus Virus-Associated RNA and Translation Control", <i>Journal of Virology</i> , Vol. 65, No. 11, pages 5657-5662, Nov. 1991.	
		Imani, et al., "Inhibitory activity for the interferon-induced protein kinase is associated with the reovirus serotype...protein", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 85, pages 7887-7891, November 1988.	
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		Csatary, et al., "Attenuated Veterinary Virus Vaccine for the Treatment of Cancer", <i>Cancer Detection and Prevention</i> , Vol 17, No. 6, pages 619-627, 1993.	
		Cassel, et al., "Newcastle Disease Virus as an Antineoplastic Agent", <i>Cancer</i> , Vol. 18, No. 7, pages 863-868, July 1965.	
		Schirrmacher, et al. "Successful application of non-oncogenic viruses for antimetastatic cancer immunotherapy", <i>Institut für Immunologie und Genetik am Deutschen Krebsforschungszentrum</i> , 6900 Heidelberg, Germany, pages 19-49, March 13, 1986.	
		Lorenz, et al., "Newcastle Disease Virus as an Antineoplastic Agent: Induction of Tumor Necrosis Factor- x and Augmentation of Its Cytotoxicity", <i>Journal of the National Cancer Institute</i> , Vol. 80, No. 16, pages 1305-1312, October 19, 1988.	

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		Reichard, et al., "Newcastle Disease Virus Selectively Kills Human Tumor Cells", Journal of Surgical Research, Vol 52, pages 448-453, 1992.	
		Eaton, et al., "Contribution of Antiviral Immunity to Oncolysis by Newcastle Disease Virus in a Murine Lymphoma", Journal of the National Cancer Institute, Vol. 39, No. 6, December 1967.	
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		Cassel, "A Phase II Study on the Postsurgical Management of Stage Malignant Melanoma with a Newcastle Disease Virus Oncolysate", Cancer, Vol. 52, pages 856-860, September 1, 1983.	
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		Eaton, et al., "Autoimmunity Induced by Injection of Virus-Modified Cell Membrane Antigens in Syngeneic Mice", Infection and Immunity, Vol. 15, No. 1, pages 322-328, January 1977.	

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		Wheelock, et al, "Observation on the Repeated Administration of Viruses to a Patient with Acute Leukemia", The New England Journal of Medicine, Vol. 271, No. 13, pages 645-651, September 24, 1964.	
		Csatary, "Viruses in the Treatment of Cancer", The Lancet, page 825, October 9, 1971.	
		Kenney, et al., "Viruses as Oncolytic Agents: A New Age for "Therapeutic" Viruses?", JNCL Editorial Issue 16, pages 1-3, June 20, 1997.	
		Rodriguez, et al., "Prostate Attenuated Replication Competent Adenovirus (ARCA) CN706: A Selective Cytotoxic for Prostate-specific Antigen-positive Prostate Cancer Cells", Cancer Research, Vol. 57, pages 2559-2563, July 1, 1997.	
		Martuza, "Novel Treatment Approach for Malignant Brain Tumors Developed at Gerogetown", Georgetown University Medical Center, pages 1-8, October 1995.	
		Mineta, et al., "Attenuated multi-mutated herpes simplex virus-1 for the treatment of malignant gliomas", Nature Medicine, Vol. 1, No. 9, pages 938-943, September 1995.	
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		Ganly, et al., "Phase I trial of intratumoral injection with an E1B-attenuated adenovirus, ONYX-015, in patients with recurrent p53(-) head and neck cancer", Proceedings of ASCO, Vol. 16, page 433a, 1997. Abstract 1362.	
		Kirn, et al., "ONYX-015, A selectively replicating adenovirus, has antitumoral activity following IV administration alone and in combination with chemotherapy", Proceedings of ASCO, Vol. 16, page 433a, 1997. Abstract 1564.	
		Izbicka, et al., "Effects of ONYX adenovirus preparations on human tumor colony forming units", Proceedings of ASCO, Vol. 16, page 433a, 1997. Abstract 1554.	
		Kirn, et al., "ONYX-015 selectively replicates in and lyses cells lacking functional p53", Proceedings for the American Association for Cancer Research, Vol. 37, page 352, March 1996. Abstract 2400.	

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		Field, et al., "The pathogenicity of thymidine kinase-deficient mutants of herpes simplex virus in mice", J. Hyg., Camb., Vol. 81, pages 267-277, 1978.	
		Spriggs, et al., "Attenuated reovirus type 3 strains generated by selection of haemagglutinin antigenic variants", Nature, Vol. 297, pages 68-70, May 6, 1982.	
		Goldstein, et al., "Factor(s) Presented in Herpes Simplex Virus Type 1-Infected Cells Can Compensate for the Loss of the Large Subunit of the Viral Ribonucleotide Reductase: Characterization of an ICP6 Deletion Mutant", Virology, Vol. 166, pages 41-51, 1988.	
		Perkus, et al., "Deletion of 55 Open Reading Frames from the Termini of Vaccinia Virus", Virology, Vol. 180, pages 406-410, 1991.	
		Meignier, et al., "In Vivo Behavior of Genetically Engineered Herpes Simplex Viruses R7017 and R7020. II. Studies in Immunocompetent and Immunosuppressed Owl Monkeys (Aotus trivirgatus)", The Journal of Infectious Disease, Vol. 162, pages 313-312, 1990.	
		Hughes, et al., "Vaccinia Virus Encodes an Active Thymidylate Kinase that Complements a cdc8 Mutant of Saccharomyces cerevisiae", Journal of Biological Chemistry, Vol. 266, No. 30, pages 20103-20109, October 25, 1991.	
		Kerr, et al. "Vaccinia DNA ligase complements Saccharomyces cerevisiae cdc9, localizes in cytoplasmic factories and affects virulence and virus sensitivity to DNA damaging agents", The EMBO Journal, Vol. 10, No. 13, pages 4343-4350, 1991.	
		Clark, et al. "Protective Effect of WC3 Vaccine Against Rotavirus Diarrhea in Infants During a Predominantly Serotype 1 Rotavirus Season", Journal of Infectious Diseases, Vol. 158, No. 3, pages 570-587, September 1988.	
		Takafuji, et al., "Simultaneous Administration of Live, Enteric-Coated Adenovirus Types 4, 7, and 21 Vaccines: Safety and Immunogenicity", Journal of Infectious Diseases, Vol. 140, No. 1, pages 48-53, July 1979.	
		Taylor, et al., "Virus-Induced Regression of Tumor Growth", Journal of the National Cancer Institute, Vol. 44, pages 515-519, March 1970.	
		Beattie, et al., "Host-Range Restriction of Vaccinia Virus E3L-Specific Deletion Mutants", Virus Genes, Vol. 12, No. 1, pages 89-94, 1996.	

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Sheet 10 of 14

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Application Number	10/743,639
Filing Date	December 22, 2003
First Named Inventor	John C. Bell
Group Art Unit	1645
Examiner Name	Robert A. Zeman
Attorney Docket Number	18003-D1

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		Howard, et al., "Retrovirus-Mediated Gene Transfer of the Human....Gene: A Therapy for Cancer", Annals New York Academy of Sciences, Duke University Medical Center, pages 167-187.	
		Suskind, et al., US Dept. of Health, Education & Welfare, N.I.H., National Institute of Allergy and Infectious Disease, and N.C.I., Bethesda, MD., "Viral Agents Oncolytic for Human Tumors in Heterologous Host: Oncolytic Effect of Coxsackie B. Viruses, pages 309-318, October 29, 1956.	
		Bluming, et al., "Regression of Burkitt's Lymphoma...Association with Measles Infection" The Lancet, pages 105-106, July 10, 1971.	
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		Shingu, "Therapeutic effects of bovine enterovirus infection on rabbits with experimentally induced adult T cell leukaemia", Journal of General Virology, Vol. 72, pages 2031-2034, 1991.	
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		Holzaepfel, et al., "The Use of APC3 Virus as a Cancericidal Agent", Cancer, Vol. 10, Pages 577-580, May-June 1957.	
		Smith, et al., "Studies on the Use of Viruses in the Treatment of Carcinoma of the Cervix", Cancer, Vol. 9, pages 1211-1218, November -December 1956.	
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Application Number	10/743,639
Filing Date	December 22, 2003
First Named Inventor	John C. Bell
Group Art Unit	1645
Examiner Name	Robert A. Zeman

Attorney Docket Number 18003-D1

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		Kalvakolanu, et al., "Differentiation-dependent activation of interferon-stimulated gene factors and transcription factor NF- κ B in mouse embryonal carcinoma cells", Proc. Natl. Acad. Sci. USA, Vol. 90, pages 3167-3171, April 1993.	
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		Zhang, et al., "Gene Therapy with an adeno-associated virus carrying an Interferon gene results in tumor growth suppression and regression", Cancer Gene Therapy, Vol. 3, No. 1, pages 31-38, 1996.	
		Peplinski, et al., "Prevention of Murine Breast Cancer by Vaccination with Tumor Cells Modified by Cytokine-Producing Recombinant Vaccinia Viruses", Annals of Surgical Oncology, Vol. 3, No. 1, pages 15-23.	
		Cotran, et al., "Kinetics of Tumor Cell Growth", Robbins Pathologic Basis of Disease, 4th Edition, page 251.	
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		Tait, et al., "A Phase I Trial of Retroviral BRCA1sv Gene Therapy in Ovarian Cancer", Clinical Cancer Research, Vol. 3, pages 1959-1968, November 1997.	
		Martuza, et al., "Experimental Therapy of Human Glioma by Means of a Genetically Engineered Virus Mutant", Science, Vol. 252, pages 854-855, May 10, 1991.	
		Hanson, et al., "Identification of Vaccine Strains of Newcastle Disease Virus", Science, Vol. 122, pages 156-157, July 22, 1955.	
		Chambers, et al., "Comparison of genetically engineered herpes simplex viruses for the treatment of brain tumors in a scid mouse model of human malignant glioma", Proc. Natl. Acad. Sci. USA, Vol. 92, pages 1411-1415, February 1995.	

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Application Number	10/743,639
Filing Date	December 22, 2003
First Named Inventor	John C. Bell
Group Art Unit	1645
Examiner Name	Robert A. Zeman
Attorney Docket Number	18003-D1

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		Asada, "Treatment of Human Cancer with Mumps Virus", Cancer, Vol. 34, pages 1907-1928, December 1974.	
		Sreevalsan, "Chapter 14 Biologic Therapy with Interferon-x and B: Preclinical Studies", Biologic Therapy of Cancer: Principles and Practice, pages 347-364.	
		Stoner, et al., "Effect of Neuraminidase Pretreatment on the Susceptibility of Normal and Transformed Mammalian Cells to Bovine Enterovirus 261", Nautre, Vol. 245, pages 319-320, October 12, 1973.	
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		Gresser, et al., "Exogenous Interferon and Inducers of Interferon in the Treatment of Balb/c Mice inoculated with RC19 Tumor Cells", Nature, Vol. 223, pages 844-845, August 1969.	

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Group Art Unit	1645
Examiner Name	Robert A. Zeman

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		Csatary, et al., "Virus Vaccines for the Treatment of Cancer", Orvosi Hetilap, Vol. 131, pages 2585-2588, 1990.	
		Eck, et al., "Gene-Based Therapy", Goodman & Gilman's The Pharmacological Basis of Therapeutics, Ninth Edition, Chapter 5, 1996.	
		Lorenz, et al., "Complete Regression of Human Fibrosarcoma Xenografts after Local Disease Virus Therapy", Cancer Research, Vol 54, pages 6017-6021, December 1, 1994.	
		Lorenz, et al., "Complete Regression of Human Neuroblastoma Xenografts in Athymic Mice after Local New Castle Disease Virus Therapy", Journal of the National Cancer Institute, Vol. 86, No. 169, pages 1228-1233, August 17, 1994.	
		Ahlert, et al., "Isolation of a Human Melanoma Adapted Newcastle Disease Virus Mutant with Highly Selective Replication Patterns", Cancer Res., Vol 50, pages 5962-5968, 1990.	
		Abraham, et al., "The Murine PKR Tumor...", Experimental Cell Research, Vol. 244, pages 394-404, 1998, Article No. EX 984201.	
		Abraham, et al., "Characterization of Transgenic Mice with Targeted....", The Journal of Biological Chemistry, Vol. 274, No. 9, pages 5953-5962, 1999.	
		Beretta, et al., "Expression of the protein kinases PKR...", Oncogene, Vol. 12 pages 1593-1596, 1996.	
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